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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Cesare Gianturco

Serial No. 244,669

Filed September 14, 1988

ENDOVASCULAR STENT AND
DELIVERY SYSTEM

GROUP 3B

Before the Examiner

Dalton Truluck

Group Art Unit 336

December 28, 1988

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on DECEMBER 29, 1988

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Signature DECEMBER 29, 1988

Date of Signature

SUBMISSION OF PRIMA FACIE EVIDENCE OF PRIORITY
AND PRESENTATION OF PROPOSED COUNTS IN INTERFERENCE

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

By Preliminary Amendment, filed concurrently with the present application, Applicant added new claims 31-34 in order to provoke an interference with the patent issued to Palmaz as U.S. No. 4,733,665. No evidence of prima facie entitlement to priority nor any proposed counts were submitted at that time. The present submission is offered to provide such evidence.

Enclosed are the declarations of the inventor, Dr. Cesar Gianturco, a medical doctor, and Kenneth Wright, Ph.D, who assisted in the development and reduction to practice of the present invention. These declarations clearly demonstrate a reduction to practice prior to the filing date of the Palmaz patent, November 7, 1985. The declarations include statements of fact indicating that an apparatus embodying the claimed invention was fabricated by Dr. Gianturco and that the apparatus was successfully implanted within a body passageway of a live animal by Dr. Wright at the direction of Dr. Gianturco, to fulfill the intended purpose of the apparatus. Attached to these declarations are copies of radiograph images taken of the apparatus after the

in vivo implantation of the apparatus. The declarants have attested to the accuracy and completeness of the attached copies, as well as the authenticity of the radiograph images.

Applicant is *prima facie* entitled to a judgment of priority over the Palmaz patent because the submitted declarations and radiograph images establish an actual reduction to practice of the present invention prior to the Palmaz filing date.

Applicant believes that an Interference should be declared based upon the interfering subject matter defined in claims 31-34, added to the present application by Preliminary Amendment, and defined in the following proposed counts:

PROPOSED COUNT 1:

An endovascular implant, comprising:

a tubular shaped stent having a first diameter which permits intraluminal delivery of the tubular shaped stent into a body passageway having a lumen; and

said tubular shaped stent having a second, expanded diameter, upon the application from the interior of said tubular shaped stent of an outwardly extending force, which second diameter is variable and controlled by the amount of force applied to said tubular shaped stent, at least a portion of said tubular shaped stent being deformed by the outwardly extending force to retain said tubular shaped stent with the second, expanded diameter, whereby said tubular shaped stent may be expanded to expand the lumen of the body passageway and remain therein.

PROPOSED COUNT 2:

An apparatus for intraluminally reinforcing a body passageway, comprising:
an expandable intraluminal stent; and
a catheter having an expandable, inflatable portion associated therewith and including means for mounting said expandable intraluminal stent on said expandable, inflatable portion,
whereby upon inflation of said expandable, inflatable portion of said catheter, said stent is forced outwardly into contact with the body passageway to remain therein, and the expansion of said stent is controlled by the expansion of said inflatable portion of said catheter.

PROPOSED COUNT 3:

A method for implanting a stent within a body passageway comprising the steps of:
(a) disposing the stent upon a catheter;
(b) inserting the stent and catheter within the body passageway by catheterization of said body passageway; and
(c) providing controllable expansion of the stent at a desired location within the body passageway by expanding a portion of the catheter associated with the stent to force the stent outwardly into contact with the body passageway, by deforming a portion of the stent with a force in excess of the elastic limit of the portion of the stent, to implant the stent within the body passageway.

PROPOSED COUNT 4:

A method for expanding the lumen of a body passageway comprising the steps of:

(a) inserting an endovascular stent disposed upon a catheter into the body passageway until it is disposed adjacent a desired location within the body passageway; and

(b) expanding a portion of the catheter to provide controllable expansion of the endovascular stent outwardly into contact with the body passageway, by deforming a portion of the endovascular stent with a force in excess of the elastic limit of the portion of the stent, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the endovascular stent prevents the body passageway from collapsing, and the endovascular stent remains in the passageway.

Claims 31-34 correspond exactly to Proposed Counts 1-4, respectively. Each of the elements of the claims 31-34 may be specifically applied to Applicant's disclosure as outlined in the Appendices 1a-d attached hereto.

Proposed Count 1 corresponds substantially to claims 13 and 18 of the Palmaz patent. The correspondence between Proposed Count 1 and Palmaz claim 13 is outlined in Appendix 2a. Palmaz claim 18 is identical to claim 13 with the exception that the preamble to claim 18 defines an expandable prosthesis for a body passageway, while the preamble to claim 13 defines an expandable intraluminal vascular graft. The limitations in Palmaz requiring that the implant include a plurality of intersecting elongate members has been deleted in Proposed Count 1 as a limitation immaterial to the generic invention. Likewise, the immaterial limitation that the outwardly extending force be applied radially to the stent has been stricken.

It is believed that Proposed Count 1 corresponds substantially to claims 13 and 18 of the Palmaz patent and properly defines the interfering subject matter between that patent and the claims in the present application which are not so restricted to the immaterial limitations of the Palmaz claims. §2309.01 MPEP, Ex. 19. To properly define interfering subject matter, a count need not be identical to the corresponding claim in the patent, §2306 MPEP, and should be at least as broad as the broadest of the interfering claims. §2309.01 MPEP. Proposed Count 1 is broader than either of the Palmaz claims 13 and 18 and defines interfering subject matter with both claims.

Proposed Count 2 corresponds substantially to Palmaz claims 23 and 26, as outlined in Appendix 2b attached hereto. Palmaz claim 26 is identical to claim 23 with two exceptions. First, the preamble in claim 26 defines an apparatus for expanding the lumen of a body passageway, while the preamble to claim 23 defines an apparatus for intraluminally reinforcing the body passageway. Second, the body of claim 26 refers to an expandable intraluminal vascular graft, in lieu of the expandable tubular shaped prosthesis of claim 23. The same immaterial limitations noted above (the intersecting elongate members and the radial orientation of the outward expansion) have been deleted from the Palmaz claims to produce Proposed Count 2. As for the previous count, Proposed Count 2 is broader than either of the Palmaz claims 23 and 26 and defines interfering subject matter with both claims.

Proposed Counts 3 and 4 correspond substantially to Palmaz claims 1 and 7, respectively, as demonstrated in Appendices 2c-d attached hereto. The Proposed Counts are broader in that the radial limitation to the expanding force in the Palmaz claims has been removed. Proposed Counts 3 and 4 define interfering subject matter over the Palmaz claims 1 and 7.

In view of the foregoing, Applicant submits that an interference should be declared between the present application and U.S. Patent No. 4,733,665 to Palmaz, identifying the above Proposed Counts 1-4, with corresponding claims 31-34 of the application.

Respectfully submitted,

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APPENDIX 1

CLAIM 31

31. An endovascular implant, comprising:

a tubular shaped stent having a first diameter which permits intraluminal delivery of the tubular shaped stent into a body passageway having a lumen; and

said tubular shaped stent having a second, expanded diameter, upon the application from the interior of said tubular shaped stent of an outwardly extending force, which second diameter is variable and controlled by the amount of force applied to said tubular shaped stent, at least a portion of said tubular shaped stent being deformed by the outwardly extending force to retain said tubular shaped stent with the second, expanded diameter, whereby said tubular shaped stent may be expanded to expand the lumen of the body passageway and remain therein.

APPLICANT'S
DISCLOSURE

title
page 11, lines 10-12

page 7, lines 18-21
page 8, lines 14-17

page 8, line 23 -
page 9, line 4

CLAIM 32

32. An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable intraluminal stent; and

a catheter having an expandable, inflatable portion associated therewith and including means for mounting said expandable intraluminal stent on said expandable, inflatable portion,

whereby upon inflation of said expandable, inflatable portion of said catheter, said stent is forced outwardly into contact with the body passageway to remain therein, and the expansion of said stent is controlled by the expansion of said inflatable portion of said catheter.

APPLICANT'S

DISCLOSURE

page 1, lines 14-16

page 9, line 29 -

page 10, line 1

page 11, lines 5-8

page 8, lines 14-17

page 8, lines 5-7

page 8, lines 20-22

page 9, lines 14-22

page 11, lines 5-10

CLAIM 33

33. A method for implanting a stent within a body passageway comprising the steps of:

- (a) disposing the stent upon a catheter; page 8, lines 5-17
- (b) inserting the stent and catheter within the body passageway by catheterization of said body passageway; and page 8, lines 23-24
- (c) providing controllable expansion of the stent at a desired location within the body passageway by expanding a portion of the catheter associated with the stent to force the stent outwardly into contact with the body passageway, by deforming a portion of the stent with a force in excess of the elastic limit of the portion of the stent, to implant the stent within the body passageway. page 8, line 23 -
page 9, line 4
page 9, lines 8-24

APPLICANT'S

DISCLOSURE

page 1, lines 4-5

page 11, lines 10-12

CLAIM 34

34. A method for expanding the lumen of a body passageway comprising the steps of:

(a) inserting an endovascular stent disposed upon a catheter into the body passageway until it is disposed adjacent a desired location within the body passageway; and

(b) expanding a portion of the catheter to provide controllable expansion of the endovascular stent outwardly into contact with the body passageway, by deforming a portion of the endovascular stent with a force in excess of the elastic limit of the portion of the stent, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the endovascular stent prevents the body passageway from collapsing, and the endovascular stent remains in the passageway.

APPLICANT'S

DISCLOSURE

page 11, lines 5-10

page 10, line 20 -
page 11, line 4

page 11, lines 5 - 10

page 9, lines 7-22

APPENDIX 2

COUNT 1

An endovascular implant,
comprising:

a tubular shaped stent ...

... having a first diameter which permits intraluminal delivery of the tubular shaped stent into a body passageway having a lumen; and

said tubular shaped stent having a second, expanded diameter, upon the application from the interior of said tubular shaped stent of an outwardly extending force, which second diameter is variable and controlled by the amount of force applied to said tubular shaped stent, at least a portion of said tubular shaped stent being deformed by the outwardly extending force to retain said tubular shaped stent with the second, expanded diameter, whereby said tubular shaped stent may be expanded to expand the lumen of the body passageway and remain therein.

PALMAZ CLAIM 13

13. An expandable intraluminal vascular graft, comprising:

a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongate members, at least some of the elongate members intersecting with one another intermediate the first and second ends of the tubular shaped member;

the tubular shaped member having a first diameter which permits intraluminal delivery of the tubular shaped member into a body passageway having a lumen; and

the tubular shaped member having a second, expanded diameter, upon the application from the interior of the tubular shaped member of a radially outwardly extending force, which second diameter is variable and controlled by the amount of force applied to the tubular shaped member, at least some of the elongate members being deformed by the radially, outwardly extending force, to retain the tubular shaped member with the second, expanded diameter, whereby the tubular shaped member may be expanded to expand the lumen of the body passageway and remain therein.

COUNT 2

An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable intraluminal stent; and

a catheter having an expandable, inflatable portion associated therewith and including means for mounting said expandable intraluminal stent on said expandable, inflatable portion,

whereby upon inflation of said expandable, inflatable portion of said catheter, said stent is forced outwardly into contact with the body passageway to remain therein, and the expansion of said stent is controlled by the expansion of said inflatable portion of said catheter.

PALMAZ CLAIM 23

23. An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable tubular shaped prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongate members, the expansion of the prosthesis being controllable; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, tubular shaped prosthesis on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter the prosthesis is forced radially outwardly into contact with the body passageway to remain therein, and the expansion of the prosthesis is controlled by the expansion of the inflatable portion of the catheter.

COUNT 3

A method for implanting a stent within a body passageway comprising the steps of:

- (a) disposing the stent upon a catheter;
- (b) inserting the stent and catheter within the body passageway by catheterization of said body passageway; and
- (c) providing controllable expansion of the stent at a desired location within the body passageway by expanding a portion of the catheter associated with the stent to force the stent outwardly into contact with the body passageway, by deforming a portion of the stent with a force in excess of the elastic limit of the portion of the stent, to implant the stent within the body passageway.

PALMAZ CLAIM 1

1. A method for implanting a prosthesis within a body passageway comprising the steps of:

disposing the prosthesis upon a catheter;

inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and

providing controllable expansion of the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, by deforming a portion of the prosthesis with a force in excess of the elastic limit of the portion of the prosthesis to implant the prosthesis within the body passageway.

COUNT 4

A method for expanding the lumen of a body passageway comprising the steps of:

(a) inserting an endovascular stent disposed upon a catheter into the body passageway until it is disposed adjacent a desired location within the body passageway; and

(b) expanding a portion of the catheter to provide controllable expansion of the endovascular stent outwardly into contact with the body passageway, by deforming a portion of the endovascular stent with a force in excess of the elastic limit of the portion of the stent, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the endovascular stent prevents the body passageway from collapsing, and the endovascular stent remains in the passageway.

PALMAZ CLAIM 7

7. A method for expanding the lumen of a body passageway comprising the steps of:

inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and

expanding a portion of the catheter to provide controllable expansion of the intraluminal graft radially outwardly into contact with the body passageway, by deforming a portion of the intraluminal graft with a force in excess of the elastic limit of the portion of the prosthesis, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen, and the intraluminal graft remains in the passageway.